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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/670,618	09/25/2003	Stephen T. Flock	D6476	6784

7590 10/04/2005

Benjamin Aaron Adler
ADLER & ASSOCIATES
8011 Candle Lane
Houston, TX 77071

EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/670,618	Applicant(s) FLOCK ET AL.	
	Examiner Michael J. Hayes	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 July 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6,8,13-26,28-32,34-37,43,44,50,51,61 and 62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6,8,13-26,28-32,34-37,43,44,50,51,61 and 62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/07/05 has been entered.

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the container operably connected to the device for supplying the abrasive as recited in claim 1 or connected to collect biomolecules as recited in claim 30 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the

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renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification is not enabling how a pressurized gas, explosive discharge, rheologic materials, or shape-memory materials function as a means to drive an abrasive member at high frequencies. How one is able to attain high frequency driving forces using these methods and/or materials is not enabled in the specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

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A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1, 2, 4, 5, 6, 8, 14, 18, 19, 21-26, and 62 are rejected under 35 U.S.C. 102(b) as being anticipated by SUROFF (US Patent No. 5,150,492). Suroff discloses a device for altering tissue comprising an abrasive member contacting abrasive material on tissue or thereon and means to drive the member at high frequency. The device is capable of use with various tissues and various lubricant (i.e., water) and pharmaceuticals.

Claims 1, 2, 4-6, 8, 13-18, 20-26, and 62 are rejected under 35 U.S.C. 102(a) as being anticipated by BERNAZ (WO 02/053046) (See US Pub. No. 2004/0092959 for English version). Bernaz discloses a device for altering or ablating tissue comprising an abrasive member contacting abrasive material on tissue or thereon, electro or magneto responsive material (motor) means to drive the abrasive member at high frequency, abrasive material of aluminum oxide 50-90 microns, lubricant comprising water, electrophoretic driving means, and a container formed by ridges capable of holding pharmaceuticals until delivery by mechanical pressure. See 2004/0092959 paragraphs 0019, 0025, 0031, 0032, 0046-0047, 0052, 0055, 0062, and 0063. The device is capable of use with various tissues and pharmaceuticals.

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Claims 1, 2, 4-6, 8, 13-26, 28, 30, 31, 34-37, 43, 44, and 62 are rejected under 35 U.S.C. 102(e) as being anticipated by WEAVER (US Pub. No. 2002/0065533 A1). Weaver discloses a device for ablating tissue using an abrasive member (microparticle) that can be driven at high frequencies to contact abrasive material (microparticles) delivered onto a tissue via a container (0042-0045). The pressurized gas driving forces disclosed by Weaver are capable of driving microparticles at high frequencies by using intermittent driving forces. Weaver discloses means to deliver a pharmaceutical to the tissue (0113-0117) that inherently includes a container and can be applied using electrophoresis. The microparticles include ice and aluminum oxide with sizes within 30-120 microns (0034, 0055-0063). The gas carrier serves as a lubricant with the microparticles so they flow easily; also blood and other body fluids (i.e., lipids) provide an electrically conductive lubricant. Weaver discloses collecting biomolecules for sampling (0114), and electrodes, conductive fluid interface, and controller capable of monitoring electrical property of the tissue (0017, 0018). Re claim 37, the device disclosed by Weaver is capable of performing the claimed function of monitoring. Weaver discloses a radiant energy source, light detector and controller capable of monitoring a change in optical property of the tissue.

Claims 1, 2, 4-6, 8, 13, 14, 17, and 20-25 are rejected under 35 U.S.C. 102(e) as being anticipated by HICKOK et al. (US Pub. No. 2003/0096213). Hickok discloses a device for ablating tissue using diamond abrasive on the ablating device and a supply of pharmaceuticals to be delivered to the ablation site.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34, 35, 36, and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ as applied to claims 26 and 1 above, and further in view of EGGERS (US Patent No. 6,066,134). Bernaz discloses the claimed invention except for monitoring feedback using an electrical property of the tissue with the device. Eggers teaches monitoring feedback using a heartbeat to perform a safe ablation procedure. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Eggers in the device of Bernaz to increase the safety of the ablation procedure for better patient outcome.

Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over WEAVER as applied to claim 1 above, and further in view of EGGERS (US Patent No. 6,159,194). Weaver discloses the claimed invention including monitoring temperature, but is silent on the structure relied upon to monitor the temperature (0117). Eggers teaches monitoring a thermal property of the tissue using infrared sensors. The use of an infrared detector and controller analyze the data from an energy source and detector is inherent in the disclosed device because it measures temperature. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Eggers in the device of Weaver in order to maintain safe operating temperatures during the ablation procedure.

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Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ, WEAVER, or HICKOK as applied to claim 20 above, and further in view of UNGER (US Patent No. 6,416,740). Bernaz, Weaver, or Hickok disclose the claimed invention except for a reservoir with a permeable membrane to release a pharmaceutical to the tissue. Unger teaches the use of a permeable membrane to release the pharmaceutical in a patch applied to the skin of a patient (see 69:11-14). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Unger in the device of Bernaz, Weaver, or Hickok in order to provide a convenient drug delivery system through the skin to achieve therapeutic results.

Claims 19, 61, and 62 are rejected under 35 U.S.C. 103(a) as being unpatentable over BERNAZ, WEAVER, or HICKOK as applied to claim 1 above, and further in view of MELBOUCI et al. (US Patent No. 6,562,090). Bernaz, Weaver, or Hickok disclose the claimed invention except for using a lubricant of water and glycerol with the abrasive. Melbouci teaches using water and glycerol as a lubricant to provide a stabilized suspension of abrasive in lubricant (see claim 1). It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Melbouci in the device of Bernaz, Weaver, or Hickok in order to facilitate the flow of the abrasive.

Claim 32 is rejected under 35 U.S.C. 103(a) as being unpatentable over WEAVER as applied to claim 31 above, and further in view of FUISZ (US Patent No. 3,918,433). Weaver discloses the claimed invention except for using cotton with the collection container. Fuisz teaches using cotton in a collection container to provide sorption capacity in excess of the container volume. It would have been obvious to one of ordinary skill in the art at the time of

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the invention to use the teachings of Fuisz in the device of Weaver to provide for a collection container to hold fluid.

Response to Arguments

Applicant argues that Suroff does not disclose a device effective to ablate tissue. The examiner disagrees because the device disclosed by Suroff is capable of ablating tissue, even if a particular method of ablating tissue is not described. Applicant's claims are directed to a device and not a method, and therefore any functional limitations must be capable of being performed by the prior art, not explicitly stated as being performed as in method steps.

Applicant argues that Suroff or Bernaz do not disclose means to deliver a pharmaceutical to tissue. The examiner disagrees and refers to cavities seen in the disclosed devices that are capable of containing pharmaceuticals and structure that is capable of applying mechanical pressure to deliver the pharmaceuticals. Applicant does not positively claim a pharmaceutical, but rather, structure that would be capable of delivering a pharmaceutical.

Applicant's arguments directed at the procedures disclosed in the prior art focuses on prior art methods. This focus is misplaced; the focus should be on the structure disclosed in the prior art as well as its capabilities.

Applicant argues that the references do not disclose monitoring an electrical or thermal property of tissue with depth of ablation; however, this limitation is not recited in the claims. There is no recitation of monitoring with depth of ablation. Even if this limitation were recited the prior discloses structure that is capable of performing such a function.

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Applicant argues that use of a patch in the device of Bernaz would render Bernaz inoperable. The examiner maintains the rejection because Unger is not relied upon for teaching a patch, but rather a reservoir with a semi-permeable membrane.

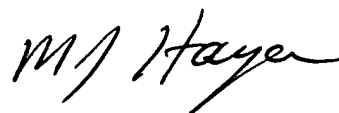
Applicant argues that Bernaz nor Melbouci teach an electrically conductive lubricant. The examiner maintains the rejection because the blood in contact with the abrasive comprises an electrically conductive lubricant at the ablation site.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (571) 272-4959. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi, can be contacted at (571) 272-4977. The fax number for submitting official papers is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

mjh
26 September 2005



MICHAEL J. HAYES
PRIMARY EXAMINER